K090008

510(k) Summary of Safety and Effectiveness

Submitted by:

Pharos Life Corporation
11-380 Jamieson Parkway
Cambridge, Ontario
N3C 4N4

1. **Date Prepared:**
   July 16, 2009

OCT 15 2009

2. **Contact Person:**
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3. **Device Name and Classification:**

Device	Lamp, infrared, therapeutic heating
Regulation Description	Infrared lamp
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	ILY
Submission Type	510(k)
Regulation Number	890.5500
Device Class	2

4. **Intended Use:**
   The Tända Restore System is an over-the-counter device intended for use whenrever hot applications are desirable for personal comfort and whenever recommended by a licensed medical professional for the purpose of providing temporary relief of minor aches and pains in muscles and joints.

5. **Substantial Equivalence:**

Predicate Device Name(s)	Applicant	510(k) Number	Date of FDA Clearance
Light Relief Pain Relief Device	Light Relief, LLC	K070974	May 24, 2007
MedX	MedX Health Corp	K020017	July 12, 2002
Quantum WARP 10 Light Delivery System	Quantum Devices	K032229	Nov 3, 2003

6. **Device Description**

The Tanda Restore is a modular platform which supports and infrared lamp (LED Array Head) for the purposes of applying infrared heat to the human body. It consists of LED infrared lamps emitting infrared energy in the wavelength of 870 nm.

7. **Comparison of Technological Differences**

The intended use and technological characteristics of the Tanda Restore are virtually identical to the combined intended uses and technological characteristics of the listed equivalent predicate devices. Any differences between the Tanda Restore System and the equivalent devices have no significant influence on the safety or effectiveness of the Tanda Restore System.

8. **Additional Safety Data**

The Tanda Restore System has undergone certification to IEC 60601-1. In addition, testing and analysis have demonstrated compliance to ISO 10993 (biocompatibility).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Pharos Life Corporation
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

OCT 15 2009

Re: K090008
Trade/Device Name: Tända Restore™
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: September 29, 2009
Received: September 30, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: **Tända Restore™**

Indications For Use:

Tända Restore is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating and/or maintaining tissue temperature. Use wherever heat application is prescribed for personal comfort and the temporary relief of minor muscular pain, joint pain and stiffness. Provides temporary relief of minor aches and pains in muscles and joints. Aids in the relaxation of muscles. Helps provide a temporary improved range and freedom of motion due to muscle relaxation and temporary minor pain relief. Provides a temporary increase in local blood circulation.

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)
		X

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090008